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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,341	12/18/2000	Gary W. Hall	349-003	5178

45848 7590 12/20/2005

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EXAMINER

HARTMAN JR, RONALD D

ART UNIT PAPER NUMBER

2121

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/740,341

Applicant(s)

HALL, GARY W.

Examiner

Ronald D. Hartman Jr.

Art Unit

2121

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-22 are presented for further examination.

Response to Arguments

2. Applicant's arguments filed on 10/3/2005 have been fully considered but they are not persuasive for the following reason(s):

First, the applicant has argued that Figures 7B and 7C are not prior art, however, the specification, as originally filed, does not contain either one of these Figures. Although there appears to be reference to a Figure 7B and 7C in the specification, see specifically [0086], there are no such Figures presented in the drawings. Furthermore, [0086] refers simply to "an insertion" as element 61B, wherein Figure 7 only shows an element 61, and therefore the Examiner has interpreted these elements to be one and the same, namely, the graphical depiction of an "insertion" of some sort. That being said, since all of the Figures presented in 5,891,131 are present in the present application, since as already discussed, there is no Figure 7B and 7C, it would appear that the applicants arguments are not persuasive with respect to the invention being contemplated by Figures 7B and 7C since these Figures are not prior art.

The applicant then goes to argue that the '131 patent does not adequately disclose an insertion. The applicant is reminded that the reference must be viewed in its entirety, and the applicant is kindly asked to reread the entire specification of the '131 reference, specifically, C 1 L24-32, in which "implantation of human or synthetic materials into the corneal stroma" is discussed, and C2 L20-36, in which "corneal implants" are discussed. These "implants" are "insertions" since the applicant has already attested that the insertion is not the result of a cutting by a cutting device, i.e. "an incision", but rather, is something which is inserted into the cornea, otherwise known as an implant.

It is also worth noting that U.S. Patent No 5,766,016 also teaches a computerized method for simulating corneal implants and was published more than one year prior to the effective filing date of the instant application.

Therefore, since the claims have not been amended in such a way to read around the applied "Prior Art", and since the applicants arguments were not persuasive for the reasons already mentioned above, this action is being made FINAL, and the maintained rejections, including the discussion of the newly added features of amended claims 1, 2, 4, 6, 20, 21 and 22, to include a feature wherein "an increased stiffness" is associated with "the insertion" have been repeated and included herein, below, for the applicants convenience below.

Specification

3. The specification is objected to because page 23, line 17, and the reference to "Figs 7B and 7C" should be deleted since Figures 7B and 7C are not present in the application. Page 23, line 18, "Fig 7B" should be deleted and line 20, the blank line should be deleted as well. Page 24, line 9, "Fig 7C" should be deleted for the same reasons.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the claimed "insertion", element 61B, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

Art Unit: 2121

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103 (maintained)

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajan et al., U.S. Patent No. 5,891,131.

Claim 1 sets forth the same features as claim 1 of U.S. Patent No. 5,891,131 except that U.S. Patent No. 5,891,131 does not specifically teach simulating a "strain relationship produced by... corneal deformation in response to..." but rather teaches "simulating corneal deformation in response to..."

Therefore, since the strain relationship is merely a "strain value" that is derived from corneal deformations, although it is not specifically mentioned, it is an obvious variation of simply acquiring "a value" and therefore it is an obvious variation of step (c) wherein "a value is determined and this value is assigned to each element".

Furthermore, with regards to the applicants amendments of claims 1, 2, 4, 6, 20, 21 and 22, the inclusion of the "increased stiffness" and the addition of the "insertion" are features inherent to the determining the strain relationship, as discussed by 5,891,131 since clearly, if an insertion, as claimed, is placed in the eye, an increased stiffness will be experienced by the surrounding tissue, and the disclosed invention discussed by 5,891,131 adequately contemplates this functional capability by contemplating the use of corneal implants (e.g. C1 L24-32 and C2 L20-36) and by calculating a strain value, as already discussed.

As per pending claim, step (a) is adequately disclosed by 5,891,131 (e.g. C14 L22-26), step (b) is adequately disclosed by 5,891,131 (e.g. C14 L27-30), step (c) is adequately disclosed by 5,891,131 (e.g. C14 L31-34), step (d) is adequately disclosed by 5,891,131 (e.g. C14 L35-39), and step (e) is adequately disclosed by 5,891,131 (e.g. C14 L40-43).

The only discernable difference appears to be that pending claim 1 claims an "insertion", whereas patented claim 1 refers to "an incision". However, in light of the specification of 5,891,131, specifically, C1 L24-32 and C2 L20-36, it would have been obvious to one of ordinary skill in the art to have utilized the simulating features of 5,891,131 for corneal insertions, or implants, in addition to utilizing the simulations for incisions to as to allow a simple, effective way of simulating common, complicated surgeries so as to allow a surgeon the ability to practice his or her skills without needing to practice on an actual human being, and this would have been obvious to one of ordinary skill in the art at the time the invention was made.

Claim 2 sets forth the same features or limitations as in claim 2 of U.S. Patent No. 5,891,131 except for the minor differences already explained by way of claim 1 above. Furthermore, although claim 2 teaches "changing the z coordinate of the nodes ..." and claim 2 of U.S. Patent No. 5,891,131 does not, this feature would obviously take place in order to effectively back calculate the necessary values, and therefore its inclusion would have been obvious to one of ordinary skill in the art at the time the invention was made.

Claim 3 claims essentially the same limitations and or features as claimed in claim 3 of U.S. Patent No. 5,891,131.

Claim 4 sets forth the same features or limitations as claim 4 of U.S. Patent No. 5,891,131 except for the minor differences already explained by way of claim 1 above. In addition, claim 4 refers to a physical change while claim 4 of 5,891,131 refers to a corneal ablation; however, an ablation is a physical change, See Background of

Invention and Col. 13, lines 7-12. Furthermore, step (d) refers to "thermal shrinkage of a portion" while step (d) of U.S. Patent No. 5,891,131 refers to "an ablated portion". Since an ablation would obviously be formed by way of thermal shrinkage, via the claimed incisions, its use would have been equally obvious to one of ordinary skill in the art at the time the invention was made.

Claim 5 essentially sets forth the same limitations as claim 5 of U.S. Patent No. 5,891,131 except for the minor differences with respect to ablation and thermal shrinkage, which was already discussed above with regards to claim 4 and is applied equally herein.

Claim 6 sets forth the same features or limitations as claim 6 of U.S. Patent No. 5,891,131 except for the minor differences already explained by way of claim 1 above.

Claim 7 sets forth essentially the same features or limitations as claim 7 of U.S. Patent No. 5,891,131.

Claim 8 sets forth essentially the same features or limitations as claim 8 of U.S. Patent No. 5,891,131.

Claim 9 sets forth essentially the same features or limitations as claim 9 of U.S. Patent No. 5,891,131.

Claim 10 sets forth essentially the same features or limitations as claim 10 of U.S. Patent No. 5,891,131.

Claim 11 essentially sets forth the same limitations as claim 11 of U.S. Patent No. 5,891,131 except for the minor differences with respect to ablation and thermal shrinkage, which was already discussed above with regards to claim 4 and is applied equally herein.

Claim 12 sets forth essentially the same features or limitations as claims 12 and 13 of U.S. Patent No. 5,891,131.

Claim 13 sets forth essentially the same features or limitations as claim 14 of U.S. Patent No. 5,891,131.

Claim 14 sets forth essentially the same features or limitations as claim 15 of U.S. Patent No. 5,891,131.

Claim 15 sets forth essentially the same features or limitations as claim 16 of U.S. Patent No. 5,891,131.

Claim 16 sets forth essentially the same features or limitations as claim 17 of U.S. Patent No. 5,891,131.

Claim 17 sets forth essentially the same features or limitations as claim 18 of U.S. Patent No. 5,891,131.

Claim 18 sets forth essentially the same features or limitations as claim 19 of U.S. Patent No. 5,891,131.

Claim 19 sets forth essentially the same features or limitations as claim 20 of U.S. Patent No. 5,891,131.

Claim 20 sets forth the same features or limitations as claim 21 of U.S. Patent No. 5,891,131 except for the minor differences already explained by way of claim 1 above, as well as the minor differences with respect to ablation and thermal shrinkage, which was already discussed above with regards to claim 4 and is applied equally herein.

Claim 21 sets forth the same features or limitations as claim 23 of U.S. Patent No. 5,891,131 except for the minor differences already explained by way of claim 1 above, as well as the minor differences with respect to ablation and thermal shrinkage, which was already discussed above with regards to claim 4 and is applied equally herein.

Claim 22 sets forth the same features or limitations as claim 24 of U.S. Patent No. 5,891,131 except for the minor differences already explained by way of claim 1 above, as well as the minor differences with respect to ablation and thermal shrinkage, which was already discussed above with regards to claim 4 and is applied equally herein.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald D. Hartman Jr. whose telephone number is (571) 272-3684. The examiner can normally be reached on Mon.-Fri., 11:00 - 8:30 pm, EST.

Art Unit: 2121

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Knight can be reached on (571) 272-3687. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ronald D Hartman Jr.

Patent Examiner

Art Unit 2121

XRDH

December 12, 2005

A handwritten signature in black ink, appearing to read 'Anthony Knight', with a stylized flourish at the end.

Anthony Knight
Supervisory Patent Examiner
Group 3600